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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,940	06/03/2005	Peter K. Law	37794-0042	4972

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EXAMINER	
POPA, ILEANA	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,940	LAW, PETER K.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-27 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24, drawn to a method of replenishing degenerated cardiomyocytes in a patient with heart disease by using heterokaryotic cardiomyocytes.

Group II, claim(s) 25-27, drawn to drawn to a composition of cells useful for the repair of damaged heart muscle, wherein the cells are myoblasts.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, **or**

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. It is noted that the instant claims are drawn to multiple products and multiple methods of using these products.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The invention of Group I is drawn to a method for producing heterokaryotic cardiomyocytes, while the invention of Grouyp II is drawn to transgenic myoblasts, which cannot be produced by the invention of Group I. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I and II do not relate to a single inventive concept under PCT rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Species Election

3. Should invention of Group I be elected for prosecution, a further species election is required as follows between patentably distinct species

Claim 23 is generic to a plurality of disclosed patentably distinct species comprising:

- angiogenesis factor, TGF-beta,vascular endothelial growth factor, fibroblast growth factor, platelet derived growth factor, angiogenin, pleiotrophin or interleukin-8.

Claim 24 is generic to a plurality of disclosed patentably distinct species comprising:

- migration factor, a scaffolding protein, PDGF, HGF, fibronectin, MMP-1, MMP-2, laminin, laminin-1, fibronectin, type I collagen, type II collagen, type IV collagen, thrombospondin-1, lecithin-oxytetracycline-collagen matrix, a galectin, galectin-1, vitronectin, or von Willebrand protein.

Applicant is required to elect a single disclosed species for each claim indicated above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Should invention of Group II be elected for prosecution, a further species election is required as follows between patentably distinct species:

Claim 25 is generic to a plurality of disclosed patentably distinct species comprising:

- angiogenesis factor, TGF-beta,vascular endothelial growth factor, fibroblast growth factor, platelet derived growth factor, angiogenin, pleiotrophin or interleukin-8.

Claims 26 is generic to a plurality of disclosed patentably distinct species comprising:

- migration factor, a scaffolding protein, PDGF, HGF, fibronectin, MMP-1, MMP-2, laminin, laminin-1, fibronectin, type I collagen, type II collagen, type IV collagen, thrombospondin-1, lecithin-oxytetracycline-collagen matrix, a galectin, galectin-1, vitronectin, or von Willebrand protein.

Claim 27 is generic to a plurality of disclosed patentably distinct species comprising:

- migration factor, a scaffolding protein, PDGF, HGF, fibronectin, MMP-1, MMP-2, laminin, laminin-1, fibronectin, type I collagen, type II collagen, type IV collagen, thrombospondin-1, lecithin-oxytetracycline-collagen matrix, a galectin, galectin-1, vitronectin, or von Willebrand protein.

Applicant is required to elect a single disclosed species for each of the claims indicated above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the composition of Group II is patentably distinct from the method of Groups I because the composition is not produced by the method. The inventions of Group I, whereas the invention of Group II is drawn to a composition for the repair of damaged heart muscle comprising myoblasts.

The species election between the different factors recited in claims 23-27 is proper because they are drawn to distinct proteins with distinct structure and mode of action. For instance, MMP-1 and MMP-2 promote angiogenesis, whereas thrombospondin-1 is an anti-angiogenic factor, von Willebrand factor is an inducer of hemostasis, and galectin-1 promotes myotube growth in regenerating skeletal muscle.

6. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Similarly, the species election is proper because they are drawn to distinct compositions that have different structure and mode of action.

Since they represent distinct subject matter, it would be unduly burdensome for the Examiner to search all the inventions and species being sought in the pending claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

Joe Woitach
AU1633